REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested.

By the foregoing amendment, claim 49, which was inadvertently canceled instead of claim 47 in the Reply of May 30, 2001 has been added back as new claim 51, and claim 50 has been canceled without prejudice or disclaimer of the subject matter recited therein. No new matter has been added.

I. Claim Objection

Claim 50 has been objected to for being a duplicate of claim 31. This objection has been rendered moot in view of the cancellation of claim 50.

II. Rejections Under 35 U.S.C. § 112

Claims 1-12, 15-26, 29-32, 48 and 50 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

Contrary to the remarks in the Office Action, there is no confusion as to whether the dosages of antiprogesterone (RU 486 or other progesterone antagonists) disclosed in the cited reference, U.S. Patent No. 6,225,297 (" '297") (which is the English language equivalent of DE

4344463A1) and the instant specification are ovulation-inhibitory or non-ovulation-inhibitory.

Applicants submit herewith, a table summarizing the inhibitory and non-inhibitory effects of varying dosages of RU-486 on ovulation. The table indicates that the ovulation inhibiting or non-ovulation inhibiting effects of RU-486 depend on the dose amount as well as the dose schedule (i.e., daily vs. weekly). For example, 2-5 mg of RU-486 administered daily will inhibit ovulation. However, the same dose (i.e., 2-5mg) administered weekly does not inhibit ovulation. Further, daily low doses of RU-486 that range from 0.1-0.5 mg also do not inhibit ovulation. Thus, the same dose of RU-486 can inhibit or not inhibit ovulation depending on whether it is administered daily or weekly, respectively.

The non-inhibitory dosage unit of 0.1 to 5 mg for RU-486 cited in '297 (column 5, lines 15-22) is administered once per week (see column 5, lines 52-57-"The product according to the invention especially provides for the administration of the respective dosage units of the competitive progesterone antagonist . . . once per week . . . ."). Thus, this particular dose range administered weekly does not inhibit ovulation as so stated in the '297 patent. On the other hand, the dose of 2 mg/day recited on page 9 of the specification will inhibit ovulation. The '297 patent also mentions that the progesterone antagonist can be administered daily, every second or every third day (column 5, lines 60-63). However, an equivalent-action dose amount is determined in an anti-gestagenic test in rabbits. Thus, based on the foregoing, there is no contradiction in the dose ranges cited by the Examiner.

With regard to ovulation-inhibitory dosages of progesterone antagonists other than RU 486: Typical ovulation-inhibitory amounts for "other competitive progesterone antagonists" disclosed in the instant specification are in the range of 0.01-30 mg (page 9, lines 22-24); and a

typical amount for one such agent, (Z)-11ß-[(4-dimethylamino) phenyl] -17ß-hydroxy-17 α- (3-hydroxy-1-propenyl)estra-4-en-3-one, lies within this range, at 0.01 to 5 mg. (see, *e.g.*, claim 14). The '297 patent discloses a non-ovulation-inhibitory dosage range of 0.1 to 50 mg for yet another antiprogestin, onapristone (11ß-[(4-dimethylamino) phenyl] -17α-hydroxy-17ß- (3-hydroxypropyl) -13α-methyl-4, 9 (10) -gonadien-3-one).

The fact that some of the values in the instantly disclosed range of ovulation-inhibitory dosages, 0.01 to 30 mg, overlap with the amounts (0.1 to 50 mg) disclosed in the cited reference as being non-ovulation inhibitory for a different antiprogestin, onapristone, is not contradictory. For one thing, onapristone is only one species of the genus of competitive antiprogesterones. As noted above, the specific dosages of each agent will vary. Thus, there is no contradiction between the two disclosures.

Therefore, the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

III. Rejections Under 35 U.S.C. § 102

Claims 1-12 and 15-26 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Stockemann et al. (DE 4344463A1). Applicants respectfully traverse this rejection.

Stockemann et al. is drawn to methods and compositions using a progesterone antagonist in a non-ovulation inhibitory dose, rather than an ovulation-inhibitory dose as instantly claimed. As discussed above and shown in the attached table, a single dose of a progesterone antagonist will have different effects if administered daily or weekly. Stockmann et al. does not disclose ovulation inhibitory doses as claimed.

Further, the cited reference does not describe an ovulation inhibiting dose of a progesterone antagonist in the context of a multiphase preparation comprising a first phase comprising a progesterone antagonist and a second phase comprising a gestagen. In order for a reference to be anticipatory, it must disclose every element of a claim. That is clearly not the case here.

Therefore, the rejection under 35 U.S.C. § 102(a) should be withdrawn.

IV. Rejections Under 35 U.S.C. § 103

Claims 1-12, 15-26, 29-32, 48 and 50 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over by Stockemann et al. (DE 4344463A1). Applicants respectfully traverse this rejection.

Stockemann et al. also does not render the instant claims obvious. As stated above, this reference does not teach ovulation inhibitory doses. Further, there is no teaching or suggestion in the cited reference that would motivate a worker to select an ovulation inhibiting dose for a progestagen antagonist and use that dose in the "combination" disclosed in the cited reference. In addition, there is no suggestion or teaching in the cited reference to motivate a skilled worker to provide the claimed combination preparation in a kit. Absent such motivation in either case, with the requisite expectation of success, the cited reference does not render the claimed invention obvious.

Therefore, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing, further and favorable action in the form of a Notice of

Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney or agent concerning such questions so that prosecution of this application may be expedited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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REFERENCE	OVULATION INHIBITED	OVULATION NOT INHIBITED
Bygdeman et al., *Acta Obstet Gynecol Scand Suppl.*, 164:75-7 (1997)		2.5mg or 5mg weekly
Cheng et al., *Zhonghua Fu Chan Ke Za Zhi*, 36(7):424-7 (2001)		5mg or 10mg weekly
Marions et al., *Fertil Steril*, 70(5):813-6 (1998)		5mg weekly
Gemzell-Danielsson et al., *Hum Reprod*, 11(2):256-64 (1996)		2.5mg or 5mg weekly
Spitz et al., *Hum Reprod*, 9 Suppl 1:69-76 (1994)		50mg weekly*
Bygdeman et al., *Acta Obstet Gynecol Scan Suppl.*, 164:75-7 (1997)		0.5mg daily
Danielsson et al., *Hum Reprod*, 12(1):124-31 (1997)		0.1mg or 0.5 mg daily
Batista et al., *Am J Obstet Gynecol*, 167(1):60-5 (1992)		1mg daily (ov. delayed)
Cameron et al., *Clin Endocrinol*, 43(4):407-14 (1995)	2mg daily	
Ledger et al., *Hum Reprod*, 7(7):945-50 (1992)	2mg or 5mg daily	
Ledger et al., *Hum Reprod*, 7(7):945-50 (1992)	25mg –600mg	
Croxatto et al., *Hum Reprod*, 8(2):201-7 (1993)	5mg or 10mg daily	
Brown et al., *J Clin Endocrinol*, 87(1):63-70 (2002)	2mg or 5mg daily	
Cameron et al., *Hum Reprod*, 11(11):2518-26 (1996)	2mg daily	
RANGE OF RU-486 (MIFEPRISTONE) USED	2-5mg/daily	2.5-10mg/weekly or 0.1-0.5mg daily (1mg daily delayed ovulation)

*Ovulation inhibition occurred in one out of three women.